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Original Article

A comparison between non-sedation and general endotracheal anesthesia for retrograde endoscopic common bile duct stone removal: A tertiary center experience

Chih-Ming Liang, Chung-Mou Kuo, Lung-Sheng Lu, Cheng-Kun Wu, Cheng-En Tsai, Ming-Te Kuo, Yi-Chun Chiu*, Wen-Chen Tai, Yuan-Hung Kuo, Chung-Huang Kuo, Seng-Kee Chuah, Chi-Sin Changchien*

Division of Hepatogastroenterology, Department of Internal Medicine, Kaohsiung Chang Gung Memorial Hospital and Chang Gung University College of Medicine, Kaohsiung, Taiwan

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ABSTRACT

Background: Conscious sedation is not routinely administered for therapeutic endoscopic retrograde cholangiopancreatography (ERCP) in many countries. The aim of our retrospective study was to compare the safety and rate of success and complications during common bile duct (CBD) stone extraction using ERCPs performed with no-sedation (NS) or under general endotracheal anesthesia (GET).

Methods: The medical records of all patients who underwent ERCP for biliary stone extraction between January 2010 and September 2013 were reviewed, and patients classified to the NS and GET groups. The primary outcomes were the rate of success of complete stone removal and rate of complications, including post-ERCP pancreatitis (PEP), perforation, bleeding, pneumonia, and mortality within 30 days post-ERCP. Operative time was recorded for analysis.

Results: During the study period, 630 patients underwent ERCP, 402 with NS and 105 with GET. Among the 402 patients in the NS group, 37 (9.2%) could not complete the procedure due to an inability to tolerate the procedure. The success rate of complete stone extraction was higher among patients in the GET group than the NS group (94.3% versus 75.6%, respectively; $p < 0.001$). The rate of contrast injection into the pancreatic duct was higher for the NS than GET group (24.9% versus 15.2%, respectively; $p = 0.008$). Although non-significant, there was a higher incidence of post-ERCP pancreatitis (PEP) in the NS than in the GET group (10.4% versus 5.7%, respectively; $p = 0.105$), while the incidence of pneumonia was higher for the GET group. Biliary pancreatitis, contrast injection into the pancreatic duct and an operation time $\geq$30 min were independent risks factors for PEP.

Conclusions: ERCP under GET is effective for CBD stone removal, but with slightly higher pneumonia rate after the procedure than non-sedated ERCP.

* *Corresponding author*. Division of Hepatogastroenterology, Kaohsiung Chang Gung Memorial Hospital, 123, Dapi Rd., Niaosong, Kaohsiung 833, Taiwan.
E-mail addresses: kuo51116@gmail.com (C.-M. Kuo), chiuku@ms14.hinet.net (Y.-C. Chiu).
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At a glance of commentary

Scientific background on the subject

Early ERCP will reduce 30-day mortality and morbidities in patients with acute cholangitis. The method of local pharynx anaesthesia become a "cannot be a choose but" an alternative method in the patients needing emergent ERCP without conscious anaesthesia evaluation, and furthermore, it was effective and safe in some report.

What this study adds to the field

37 (9.2%) patients in the non-sedation condition could not complete the procedure of stone removal due to an inability to tolerate. Performing the procedure under general endotracheal anesthesia was associated with a higher success rate of complete stone extraction from the common bile duct.

In complex, time-consuming and painful endoscopic interventions, such as endoscopic retrograde cholangiopancreatography (ERCP), conscious sedation is administered in order to diminish patient discomfort and to achieve anxiolysis and cooperation [1]. Conscious sedation has routinely been performed by gastroenterologists for therapeutic endoscopic procedures in the United States, and many other countries [2]. However, in contrast, in Asia, the Middle East, South America, and some European countries, conscious or general sedation is not routinely used for ERCP [3–5], especially in emergent patients that require immediate action, such as acute cholangitis with impacted stone or tumor compression [6,7]. Early ERCP will reduce 30-day mortality in patients with acute cholangitis, and delay ≥48 h is associated with disproportionate increase in hospital stay and additional adverse outcomes including hypotension [8,9]. The method of local pharynx anaesthesia become a "cannot be a choose but" an alternative method in the patients needing emergent ERCP without anaesthesia evaluation, and furthermore, it was effective and safe in some report [10]. In respect of anesthesia ERCP, 33%–50% of patients who undergo ERCP under conscious sedation still report pain and discomfort [11]. Moreover, the procedural failure rate in patients who undergo ERCP under conscious sedation is almost double the rate for patients in whom ERCP is performed under general endotracheal anesthesia (GET) (14% versus 7%). The higher failure rate with conscious sedation is principally due to premature termination of the procedure because of an inability of patients to tolerate the procedure under inadequate sedation [12]. Additionally, conscious sedation may easily progress to loss verbal contact once over sedation.

In view of above mentioned reasons, the anaesthesiologist conference commented the GET anaesthesia with airway protection was preferred for ERCP procedure in case of the aspiration choking in 2010. As a result, GET anaesthesia was used routinely for ERCP if patient request in our institution, although which is different than the more common use of conscious sedation in the United States [1,2,13,14]. Therefore, we conducted a retrospective study to compare the safety and rate of success and complications among patients undergoing ERCP for stone extraction from the common bile duct (CBD) under GET or non-sedation (NS).

Materials and methods

We performed a retrospective chart review of all consecutive cases of ERCP performed for CBD stone extraction, between January 2010 and September 2013, at Kaohsiung Chang Gung Memorial Hospital, Taiwan. The study was approved by both the Institutional Review Board and Ethics Committee of Chang Gung Memorial Hospital, Taiwan (IRB104-2460B). All patients were >18 years old and provided their written informed consent prior to ERCP. All procedures were performed by 5 experienced endoscopists, who each perform 100 ERCPs on average per year. Cases were screened on the following exclusion criteria: procedural failure requiring an anatomy-modifying procedure, such as a Billroth II subtotal gastrectomy or R-en-Y gastrojejunostomy (n = 11); stenosis of the pyloric ring (n = 5); tumor-related obstruction (n = 2); treatment requiring only supportive retrograde biliary drainage (n = 99); and failure to locate the papilla (n = 6).

The decision for GET or NS was based on patients' preference and experience. Patients in the NS group (n = 402, 79.3%) received local pharyngeal anesthesia, using a 2% lidocaine spray, prior to duodenoscope insertion, combined with an intramuscular injection of 30–50 mg pethidine for pain control, 10 min prior to endoscopic papillary balloon dilation (EPBD). Patients in the GET group (n = 105, 20.7%) were induced with 2.5–3.0 mg of propofol per kilogram body weight, 0.5 mg of atracurium per kilogram and 0.5–1.0 mg of alfentanil by anaesthesiologist. After endotracheal intubation, general anesthesia was maintained with 0.4–1.0% isoflurane, 70% nitrous oxide in 30% oxygen and repetitive doses of 0.1 mg of atracurium per kilogram and 0.5–1.0 mg of alfentanil. All ERCP procedures were performed using a side-view endoscope (JF 260 v and TJF 240, Olympus, Tokyo, Japan), after selective cannulation of the CBD using a cholangiography catheter (PR-113Q, Olympus) and 0.035-inch guide-wire (Zebra Exchange Guidewire, Microvasive Boston Scientific Watertown, MA). Details of the ERCP procedure have previously been reported [15].

According to the guideline commissioned by the European Society of Gastrointestinal Endoscopy (ESGE) in 2010 [16], the wire-guided technique was recommended for deep biliary cannulation. The cholangiopancreatogram was needed by occasionally before guidewire cannulation to evaluate the duct structures. In the difficult biliary cannulation patients, we would perform limited precut sphincterotomy combined with EPBD for CBD stone removal. The definition of difficult biliary cannulation in our study was as follows: (1) failed cannulation within 10 min (2) 5 passages or injections of the pancreatic duct, or (3) 10 attempts at the papilla without a time limit [17].

Complete stone removal was defined as the absence of bile duct stones confirmed by a balloon occlusion cholangiogram. The following demographic and clinical variables, recorded

prior to ERCP, were extracted from the medical records for analysis: age, sex, history of diabetes and hypertension, alcohol consumption, smoking habit, previous ERCP experience, and the American Society of Anesthesiologists (ASA) score [18]. Serum levels of amylase, lipase, total bilirubin, and liver function enzymes, as well as a complete blood count/differential count, were obtained one day before and after ERCP to assess complications. The primary outcomes were the rate of success of complete stone removal and occurrence rate of major complications (post-ERCP pancreatitis based on the modified criteria of Cotton and colleagues [19], perforation, bleeding, pneumonia, and mortality within 30 days of the procedure). Cannulation failure was defined by the following criteria: cannulation time >30 min; termination of the procedure by the operator, failure to locate the major papilla, even after adjustment of the endoscope; and patient agitation, making continuation of the procedure unsafe [19]. Operative time was defined as the time from the start of cannulation to the time of complete extraction of CBD stones.

Statistical analysis

All analyses were performed using the Statistical Package for Social Sciences (SPSS; version 18.0 for Windows). Descriptive statistics, including distributions, absolute frequencies, relative frequencies, medians and ranges, or means ± standard deviation (SD) were calculated as appropriate for the variable type. Between-group differences for quantitative variables with a normal distribution were compared using Student's *t*-test. Differences between proportions of categorical data were evaluated with Fisher's exact test when the number of expected cases was less than 5, and otherwise a chi-squared analysis was used. A multivariate logistic regression model was used to identify independent factors of procedural success and occurrence of major adverse events. A *p*-value of <0.05 was considered to be statistically significant for all analyses.

Results

The distribution of age, sex, personal habitats (alcohol consumption and smoking), ASA score, previous ERCP experience, and co-morbidities was similar between the GET and NS groups (Table 1). Among the 402 patients in the NS group, the procedure could not be completed in 37 cases (9.2%) due to the patient's inability to tolerate the procedure. These cases were completed under GET. The rate of successful completion was higher for the GET group than the NS group (94.3% versus 75.6%, respectively; $p < 0.001$). The rate of cannulation failure was higher for the NS group than the GET group (8.2% versus 0.9%, respectively; $p < 0.001$). Serum levels of aspartate aminotransferase, alanine aminotransferase and amylase were higher for the NS group than the GET group: aspartate aminotransferase, 137.2 ± 163.5 versus 93.9 ± 141 U/l., respectively, $p = 0.021$; alanine aminotransferase, 167.8 ± 189.6 versus 109.3 ± 152.7 U/l, respectively, $p = 0.0004$; and amylase, 360.4 ± 867.0 versus 195.9 ± 817.3 U/l, respectively, $p = 0.034$. A higher rate of contrast injection into the pancreatic duct was required for the NS than GET group: 24.9% versus 15.2%, respectively; $p = 0.008$. With regard to major complications, the rate of post-ERCP pancreatitis (PEP) was higher for the NS than GET, 10.4% versus 5.7%, respectively, although this between-group difference was not significant ($p = 0.105$; Table 2), while more patients developed pneumonia in the GET than in the NS group (6.7% versus 2.2%, respectively, $p = 0.029$; Table 3). Otherwise, the rate of complication was similar between the two groups, as summarized in Table 3. On univariate analysis, the following clinical factors were associated with PEP: age <50 years; biliary pancreatitis, contrast injection into the pancreatic duct, and an operative time ≥30 min (Table 4). On multivariate analysis, biliary pancreatitis (OR, 4.54; 95% CI: 1.80–11.45, $p = 0.001$), (OR, 2.79; 95% CI: 1.11–7.03, $p = 0.029$) and an operation time ≥30 min (OR, 5.60; 95% CI: 2.23–14.05, $p < 0.001$) were retained as independent predictive factors of PEP (Table 5).

Table 1 Demographic data for the two groups.

Characteristics	Non-sedation ($n = 402$) (%)	GET ($n = 105$) (%)	*p*-value
Age (year) (mean ± SD)	64.5 ± 15.0	66.4 ± 17.1	0.208
Sex (F)	172 (42.8)	50 (47.6)	0.374
Smoking	53 (13.2)	18 (17.1)	0.351
Alcohol consumption	49 (12.2)	16 (15.2)	0. 466
Diabetes Mellitus	118 (29.3)	36 (34.3)	0.419
Hypertension	159 (39.5)	50 (47.6)	0.200
ASA score I/II/II/IV	136/131/112/11 (33.8/32.6/27.9/2.7)	35/37/30/3 (33.3/35.2/28.6/2.9)	0.983
Creatinine (mg/dl)	1.8 ± 5.5	1.6 ± 3.3	0.679
AST (U/l)	137.2 ± 163.5	93.9 ± 141.7	0.021
ALT (U/l)	167.8 ± 189.6	109.3 ± 152.7	0.004
Bilirubin (mg/dl)	3.3 ± 3.2	2.8 ± 3.7	0.520
ALKP (U/l)	199.6 ± 163.9	192.1 ± 149.6	0.944
CRP (U/l)	60.3 ± 77.2	51.2 ± 75.8	0.193
Amylase (U/l)	360.4 ± 867.0	195.9 ± 817.3	0.034
Lipase (U/l)	440.9 ± 1182.4	274.9 ± 1706.7	0.169
Previous ERCP	160 (39.8)	50 (47.6)	0.250

Abbreviations: GET: general endotracheal anesthesia; ASA: American Society of Anaesthesiology score; AST: aspartate aminotransferase; ALT: alanine aminotransferase; ALKP: Alkaline phosphatase; CRP: C-reactive protein.

Table 2 Endoscopic findings and outcomes.

Characteristics	Non-sedation $n = 402$, (%)	GET $n = 105$, (%)	p-value
Pancreatic duct filling	100 (24.9)	16 (15.2)	0.008
Periampullary diverticulum	121 (30.1)	24 (22.9)	0.068
EPBD	277 (68.9)	84 (80)	0.906
EPT	77 (19.2)	27 (25.7)	0.452
Stones size (cm)	0.9 ± 0.5	1.0 ± 0.5	0.812
Stone number	1.7 ± 1.0	1.8 ± 1.2	0.011
Mean CBD diameter (cm)	1.3 ± 0.5	1.4 ± 0.5	0.759
Balloon extraction	331 (82.3)	100 (95.2)	0.278
Basket use	28 (6.9)	10 (9.5)	0.640
Causes of failure			
Bleeding	1 (0.2)	0 (0)	
Intolerance	37 (9.2)	0 (0)	
Cannulation failure	33 (8.2)	1 (0.9)	<0.001
Complex stones	27 (6.7)	5 (4.7)	
Complete stone removal	304 (75.6)	99 (94.3)	<0.001
Procedure Time (min)	25.2 ± 11.9	28.3 ± 12.9	0.189

Abbreviations: EPBD: endoscopic papillary balloon dilation; EPT: endoscopic papillotomy; CBD: common bile duct.

Discussion

ERCP uses an endoscope and electromagnetic radiation to visualize abnormalities within the bile and pancreatic ducts. ERCP is an uncomfortable procedure and, therefore, is often performed under either conscious, deep sedation or GET. A systemic review by the Cochrane Collaboration [20] reported shorter recovery time with the use of conscious sedation (midazolam and meperidine) compared to deep sedation (propofol) with, otherwise, no significant difference with regard to safety and rate of complication between conscious and deep sedation. However, the use of non-sedation for ERCP, which is relatively common in Asia, the Middle East and South American countries, has seldom been evaluated [3,4]. ERCP procedures under local xylocaine pharynx spray and intramuscular injection with meperidine were effective and safe in some report, but they did not describe the intolerance and failure rate [10]. Among the 402 (79.3%) patients who choose non-sedation ERCP initially in our study, only 37 patients (9.2%) were unable to tolerate the procedure, requiring conversion to GET to continue the ERCP. We were unable to identify the factors associated with patients' inability to tolerate the procedure in the data analysis. Similar to our findings, Raymondos et al. [11] reported a failure of the ERCP procedure due to patient agitation and intolerance of 6.1% (53/866 patients), due to inadequate conscious sedation levels, with insufficient airway protection being the cause for failure in 1.8% of cases (16/866 patients). It is worth noting that Etzkorn et al. reported a lower effectiveness of conscious sedation among patients who were multiple substance abusers [1]. Although pharyngeal anesthesia before upper endoscopy in unsedated patients has been shown to improve the ease of endoscopy and patients' tolerance of the procedure [21], inappropriate co-operation and movement increased the difficulty of biliary cannulation, resulting in a cannulation failure rate of 8.2% compared to 0.9% in sedated patients ($p < 0.001$). In our study, NS was associated with a slightly higher incidence of PEP, compared to the GET group (10.4% versus 5.7%, respectively; $p = 0.105$), but had no significant difference.

The risk factors for PEP have been well-documented in many studies [22–24]. The 2014 guidelines of the European Society of Gastrointestinal Endoscopy (ESGE) [25] identify the following procedure-specific risk factors for PEP: a duration of cannulation attempt >10 min; pancreatic guidewire passages >1 and pancreatic contrast injection. In our study, we calculated operative time from the time of the start of cannulation to CBD stone clearance, with an operative time ≥30 min being an independent risk factor for PEP. Evaluating the association between both iatrogenic and non-iatrogenic factors for PEP (Table 5), the biliary pancreatitis, and contract injection into the pancreatic duct were also independent predictive factors for PEP.

The common side effects of general anesthesia include nausea and vomiting which are usually easily treated and of short duration. However, rare but serious risks of general anesthesia must be considered, including the risk for acute coronary syndrome, heart failure, stroke, pneumonia. Although we did not identify occurrence of these important adverse events with GET in our study group, the rate of pneumonia post-ECRP was higher among patients in the GET than in the NS group (6.7% versus 2.2%, respectively, $p = 0.029$). This higher rate of pneumonia with GET is likely associated with the tracheal intubation which might inhibit the cough reflex, compromising mucociliary clearance, injure the epithelial surface of the trachea or provide a direct conduit for bacteria from the upper into the lower respiratory tract [26]. We found the patients with pneumonia was seen to associated with elder age (mean age: 72 year-old), but did not show significantly in analysis. Several preventive strategies are available to lower the risk of pneumonia, including control of the intra-cuff pressure [27], aspiration of subglottic secretions [28], use of an antiseptic impregnated endotracheal tube

Table 3 Adverse events after ERCP.

Adverse events	Non-sedation ($n = 402$) (%)	GET ($n = 105$) (%)	p-value
PEP	42 (10.4)	6 (5.7)	0.105
Bleeding	3 (0.7)	2 (1.9)	0.317
Perforation	3 (0.7)	0 (0)	0.361
Pneumonia (30 days)	9 (2.2)	7 (6.7)	0.029
Mortality (30 days)	5 (1.2)	2 (1.9)	0.652

Abbreviations: ERCP: endoscopic retrograde cholangiopancreatography; GET: general endotracheal anesthesia; PEP: post-ERCP pancreatitis.

Table 4 Univariate analysis of the clinical factors predictive of PEP.

Principle parameter		Case No.	PEP rate (no.)	P-value
Age	<50 years	79	16.4% (13)	0.033
	≥50 years	406	8.6% (35)	
Sex	Female	210	9.5% (20)	0.810
	Male	275	10.2% (28)	
Alcohol history	(–)	421	10.0% (42)	0.881
	(+)	64	9.3% (6)	
Biliary pancreatitis	(–)	260	5.8% (15)	<0.001
	(+)	73	26.0% (19)	
Sedation	Non	380	11.1% (42)	0.105
	GET	105	5.7% (6)	
EPBD	(–)	87	6.9% (6)	0.341
	(+)	351	10.3% (36)	
EPT	(–)	342	9.9% (34)	0.579
	(+)	99	8.1% (8)	
Pancreatic duct filling	(–)	337	6.2% (21)	<0.001
	(+)	114	20.2% (23)	
Operative time (min)	<30min	292	6.8% (20)	0.003
	≥30min	116	16.4% (19)	
Stone size (cm)	<1.2 cm	337	11.3% (38)	0.078
	≥1.2 cm	112	6.3% (7)	

Abbreviations: PEP: post -ERCP pancreatitis; GET: general endotracheal anesthesia; EPBD: endoscopic papillary balloon dilation; EPT: endoscopic papillotomy.

(ETT), and elimination or prevention of the biofilm formation on the ETT [29,30]. Importantly, muscle relaxation must be monitored carefully when applied and in case of insufficient return to normal at the end of a procedure.

The limitations of our study need to be acknowledged. First, this is a retrospective chart review study in which the analysis depended on the completeness of documents and images. Moreover, misrecording of variables included in the analysis is possible, such as cannulation time and number of attempts of pancreatic duct cannulation, and some data unavailable. Second, there is the possibility of inherent bias between the groups, with patients having had an unpleasant previous ERCP experience being likely to select to undergo ERCP under GET. Lastly, in the NS group, a higher proportion of patients were referred from emergency department. It is possible that these patients presented with more a more severe clinical condition, such as the presence of more severe cholangitis.

Table 5 Multivariate analysis of the clinical factors predictive of PEP.

Clinical factor	Coefficient of Variation	Odds ratio (95% CI)	*p*-value
Biliary pancreatitis	1.53 ± 0.47	4.54 (1.80 –11.45)	0.001
Pancreatic duct contrast injection	1.03 ± 0.47	2.79 (1.11 –7.03)	0.029
Operative Time (≥30 min)	1.72 ± 0.47	5.60 (2.23 –14.05)	<0.001

Abbreviation: PEP: post-ERCP pancreatitis.

In conclusions, ERCP under GET is effective for CBD stone removal, but with slightly higher pneumonia rate after the procedure than non-sedated ERCP. Biliary pancreatitis, contrast injection into the pancreatic duct and an operation time ≥30 min are independent risk factors for PEP.

Conflicts of interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bj.2019.01.002.

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